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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/550,276 | 04/15/2000 | GLENN F. SPAULDING | Cyto 1 | 9303 |

7590 05/23/2002
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EXAMINER

GABEL, GAILENE

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1641

DATE MAILED: 05/23/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,276

Applicant(s)

SPAULDING, GLENN F.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 10-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 10-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-4, without traverse, in Paper No. 8, filed 2/26/02 is acknowledged and has been entered. Claims 5-10 have been cancelled by Applicant without prejudice. Claims 10-32 have been added. Accordingly, claims 1-4 and 10-32 are pending and under examination.

Priority

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application, i.e. Provisional Application No. 60/148,139, in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specification

3. The following guideline illustrates the preferred layout for the specification of a utility application. The guideline is suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following heading prior to the description of Figure 1 in page 4 of the specification. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.

BRIEF DESCRIPTION OF THE DRAWING

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 are rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claims are replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device.

Claim 1 is confusing in reciting, "vertical rotating means ... to vertically rotate a transparent cylinder" because it is unclear how the rotating means, which is vertical, can vertically rotate the cylinder. Perhaps, Applicant intends that the vertical rotating means allows the transparent cylinder to rotate along a longitudinal axis of the vertical rotating means. Please clarify. Same analogous comments apply to claims 2-3

Claim 1 is vague and indefinite in reciting, "a light source and detector adapted to interrogate the wall of the ... transparent cylinder because it is unclear what Applicant intends to encompass in reciting, "interrogate" as used in the claim.

In claim 2, "bare code" should be --bar code.--

5. Claims 10-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 10, line 3 has improper antecedent basis problem in reciting, "a transparent cylinder" in its second occurrence in the claim.

Claim 10, line 5 is vague and indefinite in reciting, "a detector responsive to a light signal" because it is unclear what is encompassed by the term "responsive" as used in the claim.

Claim 10, line 6 has improper antecedent basis problem in reciting, "a transparent cylinder" in its fourth occurrence in the claim.

Claim 11 is vague and indefinite because it is unclear how the transparent cylinder can be sequentially rotated in two directions.

Claim 11 has improper antecedent basis problem in reciting, "a transparent cylinder".

Claim 12 has improper antecedent basis problem in reciting, "a transparent cylinder".

Claim 13 has improper antecedent basis problem in reciting, "a transparent cylinder".

The term "substantially" in claim 15 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 25 has improper antecedent basis problem in reciting, "an analog to digital converter".

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Claim 25 has improper antecedent basis problem in reciting, "a transparent cylinder".

Claim 25 lacks antecedent support in reciting, "the digital to analog value was obtained".

Claim 30 is indefinite in reciting "CCD". Acronyms or abbreviations must be recited or defined at least one time in a set of claims.

Claim 31 is vague and indefinite in reciting, "each detector responsive to a light signal" because it is unclear what is encompassed by the term "responsive" as used in the claim.

Claim 31 has improper antecedent basis problem in reciting, "a transparent cylinder".

Claim 32, line 3 has improper antecedent basis problem in reciting, "a transparent cylinder" in its second occurrence in the claim.

Claim 32, line 5 is vague and indefinite in reciting, "a detector responsive to a light signal" because it is unclear what is encompassed by the term "responsive" as used in the claim.

Claim 32, line 6 has improper antecedent basis problem in reciting, "a transparent cylinder" in its fourth occurrence in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of 37 CFR 1.71(a)-(c):

(a) The specification must include a written description of the invention or discovery and of the manner and process of making and using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

6. The specification is objected to under 37 CFR 1.71 because the limitations incorporated into claims 11-17 lack literal or descriptive support in the specification.

7. Claim 10-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In this case, the specification does not appear to provide support for "the transparent cylinder comprising: a closed end, an open end, a cell guide member, and a cap". Also, the specification does not provide any descriptive support for the rest of the limitations in claims 14-17. In page 8 of the specification, Example 16, Applicant only briefly describes that the diameter of the bottom of the cylinder (that) is narrower than the top. The specification further lacks literal and descriptive support for the recitation of "rotating means adapted to sequentially rotate the transparent cylinder in two directions" and "rotating means is adapted to rotate the transparent cylinder between

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approximately 50-3000 revolutions per minute". Lastly, there is no literal or descriptive support describing the ranges set forth in claims 19 and 23, i.e. "photoreceptor material is activated by a wavelength of *approximately 300 nm to approximately 100 nm*". In page 5 of the specification, Example 2, Applicant provides description of the inner wall of the cylinder as being modified for photo cross-linking ... using an organic photoreceptor material optimized for a wavelength of 300 nm to 2000 nm, which does not encompass the scope of the claims. Furthermore, none of the originally filed claims recited any of these limitations in question. Recitation of claim limitations lacking literal and descriptive support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1-2, 10, 13, 17, 21-22, 24-26, and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Saralegui et al. (US 5,439,645).

Saralegui et al. disclose a cytometer apparatus comprising an automatic, motor driven, and signal controlled rotating means (rotatable carousel) that holds and rotates a

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multiplicity of transparent polystyrene cylinders (test tube or glass or plastic) and wherein each cylinder carries a barcode label for identifying the specimen in the contained in the cylinder (column 1, line 64 to column 2, line 9). The carousel is provided with a central, vertically projecting handle and a movement means (self-centering lifter) for positioning along a vertical position (see column 3, lines 41-54 and see column 4, lines 5-18). Rotation is controlled by an electric stepper-type drive motor (see column 4, lines 53-55 and column 8, lines 9-11). The apparatus is also provided with a high speed barcode reader to read the coded indicia for each specimen and position sensor for identifying the position of the sample contained within the cylinder (see column 2, lines 26-31 and column). Specifically, the apparatus is provided with one or more light sources (LED, photodiodes) and detectors comprising sensing devices at fixed positions to monitor position and identification of each cylinder. Lastly, a processing means (electronic control assembly) secured to a vertical wall and a CPU controller is provided for directing automatic operations of the rotating means, the detection system, and the entire mechanical assembly (see column 3, lines 55-64 and columns 7-8).

9. Claims 1, 3-4, 10-18, 22, and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham (US 5,639,428).

Cottingham discloses an apparatus for mounting a plurality of disposable transparent cylinders (test units) in which flow of sample and reagent liquids can be controlled by centrifugal force applied by relatively simple rotating apparatus. The

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transparent cylinder comprises a sample chamber having an open end (sample port), a closed end, a guide member having a passage that extends from one end to the other, and a cap (closure or adhesive seal) for sealing the open end of the chamber. The cylinder has immobilized thereto, a reagent having a detectable element disposed in a passage (liquid flow path) for contacting with a biological sample (see column 3, lines 4-32). Specifically, the cylinder is transparent or translucent having a top film with a small opening. The cylinder has a thicker bottom portion and an adhesive seal for closure of the sample port. A passage or channel or series of channels interconnect wells within the cylinder (see column 7, line 42 to column 8, line 8). The cylinder also includes immobilized controls and standards within its inner surface in the form of dried spots (see column 9, lines 31-39). The apparatus comprises a rotating means (circular rotor) for holding and rotating the cylinders about an axis (see column 4). Above the rotor are light sources and optical detectors for illumination and detection of optical responses by the immobilized detectable reagents confined within the cylinder. Light sources include laser diode, photomultiplier tube, CCD, and further comprise diffraction grating (interference filters), lenses, shutters, etc (see column 7, lines 7-35). The transparent cylinder includes organic photoreceptor materials which may be chromogenic, fluorescent, luminescent, or radioactive depending on the substrate used (see column 14, line 64 to column 15, line 16). Lastly, the apparatus includes a processing means for operation of the mechanical assembly and for processing signal detected (see column 15, lines 58 to column 16, line 24).

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10. Claims 1, 4, 10, 13-18, 22, 26-29, and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al. (US 6,254,834).

Anderson et al. disclose a cytometric apparatus or system for characterizing microorganisms such as bacteria, virus, mycoplasma, or yeast cells in sample. The cytometric apparatus is specifically used for measuring fluorescence from the sample contained in a transparent cylinder (centrifuge tube). The apparatus comprises a rotating means (bucket) for holding and rotating the transparent cylinder, a light source such as laser, detector and optical filters for detecting light passing through or emitted from the sample (see column 10, lines 22-45). The transparent cylinder has an open end (upper region), a middle cell guide member, and a closed end (lower region) with successively smaller diameters (see columns 4-5). The open end is for receiving a sample which can be plugged with a cap and the lower end is a tubular microbanding region for isopycnically banding all the infectious particles or cells in the presence of a fluorescent dye or a combination of fluorescent dyes. Accordingly, a combination of light sources emitting at different wavelengths and detection systems can be applicable (see column 7, lines 32-41 and column 10, lines 8-21 and 46-67). Anderson et al. disclose that the inner surface of the cylinder can be modified by treatment with non-absorptive material (see column 5). The mechanical system of the apparatus and the optical signal detected from the microbanding is processed in a processing means (computer).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 19-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham (US 5,639,428) or Anderson et al. (US 6,254,834) in view of Surmodics, Inc.

Applicant, by way of disclosure at page 5, lines 17-22, admits that incorporation of photo cross-linking agents into the inner wall of cylinders, is known and used commercially by Surmodics, Inc. These photo-crosslinking agents include organic photoreceptor materials optimized for 300 nm - 2000 nm such as dibromo anthanthrone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the immobilized reagents in the transparent cylinders taught by Cottingham and Anderson to include or otherwise substitute the photoreceptor materials, i.e. chromogenic materials and luminescent materials, with dibromo anthanthrone, because SurModics specifically taught its application and suitability on inner walls of cylinders such as those used in the devices of Cottingham and Anderson. Further, the parameters set forth in claims 19 and 23 wherein "(the photoreceptor material) is activated by a wavelength of approximately 300 nm - 100 nm", constitute result effective variables which Surmodics, Inc. has shown may be obtained by optimization procedures. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a

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result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims 19 and 23 are for any particular purpose or solve any stated problem and the prior art teaches that photoreceptor materials often vary according to specific application or purpose or the sample being analyzed, the various detection materials and parametric requirements appear to work equally as well. Absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable range for dibromo anthanthrone as disclosed by the prior art by normal optimization procedures.

12. No claims are allowed.

Remarks

13. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

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Clampitt et al (US 6,127,187) disclose a cytometric apparatus comprising a centrifuge rotor, scanning arm for sending light to the sample, and a light source for colorimetric detection.

Biesel et al. (US 5,814,279) disclose a centrifuge having a drive unit, a separation chamber which can be inserted into the drive unit, and a scanning device for recognizing the position of the separation chamber which is rotated by the drive unit.

Braynin et al. disclose a plurality of peripheral cuvettes and a collection chamber spaced radially inward from the cuvettes.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday 6:00 AM to 3:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

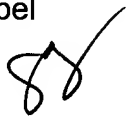
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Gailene R. Gabel

May 19, 2002



LONG V. LE
SUPERVISORY PATENT EXAMINER
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05/20/02